DEC - 5 2003

K023414

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SECTION 2. GENERAL INFORMATION

A. 510(k) SUMMARY

Summary of Safety and Effectiveness

In accordance with 21 CFR 807.92, the following information constitutes the Ortivus AB summary for the MIDA™ Algorithm Rev. B.

SUBMITTER'S NAME:	Ortivus AB
ADDRESS:	Enhagsslingan 5
	SE-187 40 Täby, Sweden
CONTACT PERSON:	Kenneth Eklund
PHONE NUMBER:	+46-8-446 45 35
FAX NUMBER:	+46-8-446 45 19
DATE OF SUBMISSION:	7 October, 2002

1. Identification of device:
   Proprietary Name: MIDA™ Algorithm Rev. B
   Common Name: Vectorcardiograph
   Classification Status: Class II per regulation 870.2400
   Product Codes: 74DYC

2. Equivalent device:
   The new device that allows the MIDA™ algorithm to use vectorcardiogram from the five leads system EASI is substantially equivalent to the MIDA™ System, Models 1000/1100 manufactured by Medical Graphics Corporation (K896396) and the HP Viridia CMS (K992595).

3. Description of the Device:
   The new device is a modification that allows the MIDA™ algorithm to use vectorcardiogram from the five leads system EASI.

4. Indication for use:
   For use only by a digital device to measure ST-segment shifts.
   Assessment of real time ST segment analysis in adult patients.
   The MIDA™ Algorithm Rev. B is intended for use in the hospital environment for the following patient population:
   Ages: 33-82 years
   Heights: 147 to 185cm (58 to 73 in.)
   Weights: 53 to 118kg (117 to 261 lbs.)
   Height to weight ratios: 1.41 to 2.99 cm/kg (0.25 to 0.54 in/lb)

   The use of EASI leads implies that the results may not be of diagnostic quality.

5. Technological characteristics, comparison to predicate device
The table below compares the MIDA B with the new predicate device (HP Viridia System) and the original MIDA.

Characteristics	MIDA 1000/1100 (K896396)	HP Viridia CMS (K992595)	MIDA Rev B (K023414)
Indications for Use	Monitor ischemia	Assessment of ST segment	Assessment of ST segment
Patient Population		Adults	Adults
Intended Use Environment	Hospital Environment	Hospital Environment	Hospital Environment
Technology	Digital	Digital	Digital
Number of Electrodes	8 Electrodes	5 Electrodes	5 Electrodes
Bandwidth	0.02 to 100 Hz	0.05 to 130 Hz	0.05 to 130 Hz
Input dynamic range	± 320 mV	± 500 mV	± 328 mV
Storage	Store data	Doesn't store data	Doesn't store data
Calculated ST-VM parameter	Yes	No	Yes
Calculated STC-VM parameter	Yes	No	Yes

5. Verification, validation and testing
The activities to establish the performance, functionality and reliability characteristics of the new device with respect to the predicate device. Testing involved acquirement of data for patients that was undergoing PTCA. Simultaneous recordings were obtained from the patient using electrode placement according to Frank and EASI. ST-segment shifts were calculated for both lead placements and compared.

6. Conclusion
Based on the Software Test Report MIDA Algorithm Rev B. ID: P-593-062., MIDA™ calculated with both Frank electrode placement and EASI electrode placement and comparison with predicate devices, it is the conclusion of Ortivus AB that the MIDA™ algorithm Rev B is substantially equivalent with the predicate device and that there is no new concerns about safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 5 2003

Ortivus AB
c/o Mr. Kenneth Eklund
Enhagsslingan 5
SE-183 25 Taby
SWEDEN

Re: K023414
Trade Name: MIDA™ Algorithm Rev. B
Regulation Number: 21 CFR 870.2400
Regulation Name: Vectorcardiograph
Regulatory Class: Class II (two)
Product Code: DYC
Dated: September 9, 2003
Received: September 12, 2003

Dear Mr. Eklund:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K023414

Device Name: MIDA™ Algorithm Rev. B

Indication for use: For use only by a digital device to measure ST-segment shifts.

Assessment of real time ST segment analysis in adult patients.

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The use of EASI leads implies that the results may not be of diagnostic quality.

Prescription Use _X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K023414